510(k) SUMMARY

Intelligent Implant Systems' Marauder™ Cervical-Thoracic Spinal Fixation System

Company Name: Intelligent Implant Systems, LLC
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Charlotte, NC 28208
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510(k) Contact: Michael Nutt
Chief Operations Officer
(704) 424-1009

OCT 2 5 2013

Date Prepared: October 23, 2013

Common Name: **Spinal Fixation System**

Classification: **888.3070, Pedicle Screw Spinal System**
888.3050, Spinal Interlaminal Fixation Orthosis

Device Class: **II**

Device Product Code: **MNI, KWP**

Predicate Devices: Aesculap: S4® Spinal Fixation System (K050979)

K2M, Inc.: MESA® Mini Spinal Fixation System (K081107)

Synthes, Inc.: Synapse System (K070573)

Intended Use / Indications for Use

Intended Use:

The Marauder™ Cervical-Thoracic Spinal Fixation System implants are intended to be used as a temporary construct that assists in normal healing and are not intended to replace normal body structures. The system is intended to stabilize the spinal operative site during posterior fusion procedures, attaching to the spine by means of hooks and screws joined with spinal rods and should be removed after fusion.

Indications for Use:

The Marauder™ Cervical-Thoracic Spinal Fixation System is intended to promote fusion of the cervical and thoracic spine (C1-T3) for the following conditions: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; spinal stenosis; trauma (fracture/dislocation); failed previous fusion; and/or tumors.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The use of screws is limited to placement in T1-T3 vertebrae for treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

Device Description

The Marauder™ Cervical-Thoracic Spinal Fixation System consists of a polyaxial bone screw with a spherical-shape head, and a standard thread for interfacing bone. Screws are available in 3.5 mm and 4.0 mm diameters and lengths from 10mm to 30mm.

In addition to polyaxial screws, hooks are provided for use in the cervical and thoracic spine. Three hook geometry variations are offered with the Marauder™ Cervical-Thoracic Spinal Fixation System. The hooks use the same rod locking means as the polyaxial screw implants.

Titanium rods are provided in various lengths and are used to connect pedicle screws and create a rigid structure. The rods are connected to the implants by interference with the rod saddle and held into position by the locking caps.

All implant components of the Marauder™ Cervical-Thoracic Spinal Fixation System are manufactured from Ti-6Al-4V alloy, conforming to ASTM F136.

Technological Characteristics

The polyaxial and rod locking mechanisms of the polyaxial screw are locked using linear force as opposed to torque. The spherical head of the screw is designed to fit within a locking spherical seat housed in the lower portion of the body. The locking mechanism utilizes an external locking sleeve that when pressed into position over the spherical seat,

compresses the spherical seat against the spherical head of the screw, locking the screw angularity of the assembly. The rod locking mechanism includes a rod saddle that is integrated in the upper portion of the body. Pressing the locking cap onto the body in turn presses the rod into the rod saddle. The cap has a tapered internal bore. When the cap is in the locked position, the tapered internal bore engages an external taper on the body, securing the cap and rod to the screw assembly. Additionally, there is a snap ring at the base of the body that snaps into an internal groove in the bore of the cap, which assists in holding the cap in position on the construct.

Performance Testing

To validate the strength and safety of the system, testing was conducted according to methods defined in ASTM F 1798, "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants", and ASTM F 1717, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model". The types of testing performed on the polyaxial screw assemblies and/or hook assemblies are listed below.

Testing per ASTM F1798-08
The following types of testing were performed on the Marauder™ Cervical-Thoracic Spinal Fixation System per ASTM F1798-08:

1. Static Flexion-Extension Strength
2. Static Rod Gripping Capacity Strength
3. Static A-P Pullout Strength

Testing per ASTM F1717-12
The following types of testing were performed on the Marauder™ Cervical-Thoracic Spinal Fixation System per ASTM F1717-12:

1. Static Compression Bending
2. Static Torsional Bending
3. Dynamic Compression Bending

Conclusions

The mechanical testing revealed that the Marauder™ Cervical-Thoracic Spinal Fixation System behaves as expected and is typical of competitive systems. In all instances, the Marauder™ Cervical-Thoracic Spinal Fixation System functioned as intended and the testing results observed were as expected.

Substantial Equivalence

Intelligent Implant Systems believes that the new Marauder™ Cervical-Thoracic Spinal Fixation System is substantially equivalent in design to:

- S4® Spinal System (K050979)
- MESA® Mini Spinal Fixation System (K081107)
- Synthes Inc. Synapse System (K070573)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 25, 2013

Intelligent Implant Systems, LLC
Mr. Michael Nutt
Chief Operating Officer
3300 International Airport Drive, Suite 1100
Charlotte, North Carolina 28208

Re: K132900
Trade/Device Name: Marauder™ Cervical-Thoracic Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: September 13, 2013
Received: September 16, 2013

Dear Mr. Nutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132900

Device Name: Marauder™ Cervical-Thoracic Spinal Fixation System

Intended Use / Indications for Use:

The Marauder™ Cervical-Thoracic Spinal Fixation System is intended to promote fusion of the cervical and thoracic spine (C1-T3) for the following conditions: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; spinal stenosis; trauma (fracture/dislocation); failed previous fusion; and/or tumors.

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132900